

## Stroke Oxygen Study

### Serious Adverse Event Notification (Assessment Form 4)

Please complete form below and fax to 0300 123 0894 and 01782 441624 ASAP within 24 hours of becoming aware of the event.

Trial name: The Stroke Oxygen Study

**ISRCTN52416964**

Report date and time (dd-mm-yyyy hh:mm) \_\_\_\_\_

Date of Enrolment \_\_\_\_\_

Centre name \_\_\_\_\_

Country \_\_\_\_\_

Randomisation number \_\_\_\_\_ Date \_\_\_\_\_ Age (years) \_\_\_\_\_ Sex: Male/female

Suspect treatment. tick the treatment you suspect as the cause of the adverse reaction:

- Oxygen 2L/min / 3L/min (please delete) inhaled via nasal cannulae  
 Oxygen 2L/min / 3L/min (please delete) for 3 nights inhaled via nasal cannulae  
 Control (room air)

#### Event information

When did this event happen with regard to the treatment phase?	Before / During / After
<b>Is it a Serious adverse event?</b>	
An adverse event is defined as serious if any of A-F has been answered with yes. Please describe the event regardless of your answer to A-F. If the answer to questions A-F is 'no' in every case this is not a serious event - Please complete form (R & D-RF-SOS-001)	
A. Did the event result in death?	Yes / No
B. Is / was the event life threatening?	Yes / No
C. Did / does the event lead to hospitalization or prolonged hospitalization?	Yes / No
D. Did / does the event result in persistent or significant disability / incapacity?	Yes / No
E. Did / does the event result in congenital anomaly / birth defect / carcinogenesis?	Yes / No
F. Does the investigator consider the event a serious adverse event for other reasons	Yes / No

A1 Date and time the Adverse Event began (dd-mm-yyyy hh:mm)	
Nature of event	Single / Multiple Episodes
Intensity of event / Grading of Serious Adverse Event	Mild / Moderate / Severe
A2 Relationship to study drug(s) / Attribution of Serious Adverse Event	Definitely not/Unrelated Unlikely / Possibly / Probably / Definitely / Unknown
A3 Action taken regarding study drug(s)	None Dose(s) missed Discontinued
A4 Clinical outcome	Recovered Not Yet Recovered Died

**B.** Please describe the event in detail, providing any relevant medical information. i.e. pathology, radiology, ECG, bacteriology, biochemistry or clinical reports / information.



## AE / SAE Event Categories v1.0

To be used with SAE form v1 amendment 2 (30. Aug.1009)

### Cardiovascular

Acute coronary syndrome (ACS)  
Atrial fibrillation (AF)  
Bradycardia  
Cardiac failure  
Cardiac dysrhythmia  
Chest pain  
Collapse  
Deep vein thrombosis (DVT)  
Hypertension  
Hypotension  
Myocardial infarction (MI)  
Pulmonary embolism (PE)  
Tachycardia  
Unstable angina

### Central nervous system

Agitation  
Anxiety  
Cerebral oedema  
Complication of initial stroke  
Dementia  
Depression  
Dysphagia  
Extension of initial stroke  
Haemorrhagic transformation (of infarct, HTI)  
Headache  
Intracerebral bleed  
Intracranial/extracerebral bleed  
Recurrent stroke  
Sedation  
Seizure  
Sensory loss  
Transient ischaemic attack (TIA)  
Vertigo  
Visual loss  
Weakness

### Cutaneous

Flushing  
Hypersensitivity inc. oropharangeal swelling, urticaria  
Rash

### Gastro-intestinal

Abdominal pain  
Constipation  
Diarrhoea  
Dysphagia  
Gastrointestinal bleed  
Gastrointestinal disturbance  
Incontinence, faecal  
Heartburn  
Hepatitis  
Nausea  
Oral ulceration  
Pancreatitis  
Vomiting  
Weight loss

### Genito-urinary

Sexual dysfunction  
Incontinence, urinary  
Renal impairment  
Urinary retention  
Urinary tract infection (UTI)

### Haematological

Anaemia  
Leukopenia  
Methaemoglobinaemia  
Thrombocytopenia

### Immunological

Anaphalactoid reaction  
Hypersensitivity

### Miscellaneous

Acid base disturbance  
Bacteraemia  
Death unattended  
Diaphoresis  
Hyponatraemia  
Hypernatraemia  
Acidosis  
Extracranial bleeding (not GI haemorrhage)  
Fall  
Fatigue  
Hyperglycaemia  
Hyperuricaemia  
Infection (not otherwise specified)  
Malignancy  
Muscle twitching  
Vascular event (not otherwise specified)

### Respiratory

Asthma  
Bronchospasm  
Chest infection  
Hypoxia  
Pneumonia  
Pulmonary embolism (PE)  
Shortness of breath

### Oxygen-related

Respiratory depression  
Drying of mucous membranes

### Other (specify)

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